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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,914	07/10/2000	Nabil Hanna	012712-905	9512

909 7590 03/11/2003
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/11/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/612,914	Applicant(s) HANNA ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,39 and 47 is/are rejected.
- 7) ☐ Claim(s) 38,40-46 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 12/17/2002 (paper no 9) is acknowledged and entered into the record. Accordingly, claims 1-36 have been canceled, and claims 37-48 are newly added.

2. Therefore, claims 37-48 are pending and examined on the record.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

3. The rejection of claims 17-21, 23-27 and 29-36 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is withdrawn in view of the cancellation and amendments to the claims submitted by the applicant.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

4. The rejection of claims 21 and 27 under 35 USC 112, 1st paragraph as lacking an enabling disclosure as it applies to the deposit of biological materials is withdrawn in view of the cancellation and amendments to the claims.

Claim Rejections Withdrawn - 35 USC § 112, 2nd paragraph

5. The rejection of claims 19,25,31, and 34 under 35 USC 112, 2nd paragraph as being indefinite is withdrawn in view of the cancellation and amendments set forth by the applicant.

Claim Rejections Maintained – Double Patenting

6. The rejection of claims 17,23, 29 (canceled) and now newly added claims 37 and 47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent 5,756,096 is maintained for the reasons of record. Applicant argues that in order to establish obviousness-type double patenting

Art Unit: 1642

that the patent office has the burden to prove two-way obviousness. Applicant's arguments have been carefully considered but is not fund persuasive because the burden is shifted to the applicant to show why a two way obviousness determination is required. Newly added claims 37 and 47 are obvious over claim 1 of U.S. Patent 5,756,096 because claim 1 recites a method of treating rheumatoid arthritis with an antibody that binds to CD-4 wherein the antigen binding domain is derived from an old world monkey and the constant domains are derived from a human. Claim 1 obviates the claims of the instant application because the species of disease treated obviates the genus of autoimmune diseases claims in the instant application. Furthermore, the antibody used in the instant application is the same or similar to that being used in U.S. Patent 5,756,096.

New Claim Rejections - 35 USC § 112, 2nd paragraph

7. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the recitation of the term "non-autoimmune", it is unclear as to what disease is to be encompassed by this term. Any disease which is not an autoimmune disease and has elevated CD4 counts is considered a non-autoimmune disease. As such, the metes and bounds of the term cannot be clearly established because the specification has not clearly defined the term.

Conclusion

8. Claims 37, 39, and 47 are rejected. Claims 38, 40-46, and 48 are objected to because they depend from rejected claims. Therefore no claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.


Application/Control Number: 09/612,914

Page 5

Art Unit: 1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
March 10, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800